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128946-0
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

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TYPE PRODUCT(S): I, D, H, F, N, R, S Microbial Pest Control Agent

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. W.Nelson (17)

PRODUCT NAME(S) Bacillus thuringiensis var. san diego M-7

M-ONE® INSECTICIDE

COMPANY NAME Mycogen Corporation

SUBMISSION PURPOSE Section 3 registration for use on potatoes, tomatoes, eggplant and elm trees to control Colorado potato beetle larvae and elm leaf beetle larvae and adults.

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
128946-0	M-ONE® INSECTICIDE (water dispersible liquid)	4.5%

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EEB Branch Review

Pesticide Name M-ONE® INSECTICIDE
(Bacillus thuringiensis var. san diego M-7)
Company code: LX 136-06

100.0.0 Submission Purpose and Label Information

100.1.0 Submission Purpose and Pesticide Use

Mycogen Corporation has requested a Section 3 registration for an insecticide with Bacillus thuringiensis variety san diego (a coleopteran killing strain) as the active ingredient for control of Colorado potato beetle larvae and elm leaf beetle larvae and adults. The crops to be treated are potatoes, tomatoes, eggplant and elm trees.

100.2.0 Formulation Information

ACTIVE INGREDIENT:	
Bacillus thuringiensis var. san diego.....	4.5 % *
INERT INGREDIENTS	95.5 %

One gallon of this product contains 0.9 lbs. of Bacillus thuringiensis var. san diego

* Equivalent to 22,500 Colorado potato beetle International Units/mg or 89 billion Colorado potato beetle International Units/gallon of this product.

100.3.0 Application Methods, Directions, Rates

(From label)

Recommended Rates and Timing

Colorado potato beetle larvae (potatoes, tomatoes and eggplant): Make first application when eghatch and small larvae are first observed. Repeat applications every 3-10 days to maintain desired control levels. Heavy larval populations will require more frequent applications.

Rates of this product will vary based on larval infestation levels and equipment* used:

Light to moderate infestation: 2-3 quarts/A*
Moderate to heavy infestation: 3-4 quarts/A*

* For aerial application the higher recommended rate should be used.

Spray Volume

Conventional ground application: mix recommended amount of product with at least 20 gallons of water per acre.

Aerial application: mix recommended amount of product with at least 3 gallons of water per acre.

For hand held equipment application mix 2 to 2.5 oz. of this product per 1 gallon of water (1.5-2% solution) to obtain uniform foliar coverage.

For control of Colorado potato beetle adults, use other approved insecticides.

Elm leaf beetle larvae and adults (elm): Make first application when egg hatch and small larvae are first observed. Repeat application as needed until desired larval or adult control levels are first reached. For light to moderate pest infestations, use 4-6 quarts of this product per 100 gallons of water (1-1.5% solution). For moderate to heavy infestations, use 6-8 quarts of this product per 100 gallons of water (1.5-2.0% solution). For best results spray to near run-off (upper and lower leaf surfaces should be thoroughly wetted).

100.4.0 Target Organisms

Colorado Potato Beetle larvae
Elm Leaf Beetle larvae and adults

100.5.0 Precautionary Labeling

The label contains the following precautions:

CAUTION: KEEP OUT OF REACH OF CHILDREN

Environmental hazards: Keep out of lakes, ponds and streams. Do not contaminate water by cleaning of equipment or disposal of wastes.

(Pesticide and container disposal directions are adequate)

101.0.0 Hazard Assessment

101.1.0 Discussion

Bacillus thuringiensis variety san diego is a recently isolated variety of Bacillus thuringiensis Berliner. It represents the first strain of this species that is toxic to coleopteran insects (beetles). Because of its recent

discovery, a large data base on susceptible insect host range is not available. Preliminary studies do show, however, that some members of the Order Coleoptera are the only host insects susceptible to the crystalline delta endotoxin. The organism does not produce the beta exotoxin thuringiensin.

Data gathered on hazards to nontarget wildlife show that this variety is as innocuous as other B.t. strains already registered. The one possible exception appears to be toxicity to wild mammals. Mouse and hamster inhalation and i.v. injection studies do show some toxicity and mortality. The toxicology branch is asking the registrant to determine the cause of these symptoms. There was no mortality to the animals via the oral and dermal routes of exposure.

No significant risk to nontarget wildlife, including mammals, is expected from exposure to the product at the registered use rates with the possible exception of endangered beetle (Coleoptera) species (see sec. 101.3.0).

101.2.0 Likelihood at Adverse Effects to Nontarget Organisms

Avian Studies

When administered by oral gavage at 0.5% (v/w) of body weight B.t. san diego had no apparent effect upon mallard ducks for 30 days. The acute pathogenicity LD_{50} value to mallards by gavage was determined to be greater than 0.5% (v/w) of body weight.

A 30 day i.p. injection study with 0.125% (v/w) a.i. in mallard ducks showed no mortalities or other abnormalities.

In view of the above, no avian hazard is expected from the proposed uses of M-ONE® insecticide containing B.t. san diego delta endotoxin.

Fish Studies

Rainbow trout 96 hr. acute toxicity tests were performed with 100 mg/L a.i. and with the formulated (4.5% a.i.) product. The LC_{50} was >100 mg/L in both tests.

In view of the above, no toxicity to freshwater fish is expected from the proposed uses of M-ONE® insecticide containing B.t. san diego delta endotoxin.

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Mammalian Wildlife

The submitted data indicate that the test substance was not toxic or pathogenic when administered by the oral, dermal or subcutaneous routes. Exposure to aerosols caused signs of toxicity that included red nasal discharge, salivation and soft stool. Mortality was observed in mice and hamsters after intravenous dosing with $\geq 5.2 \times 10^4$ CFU of the test material. Lethal effects appear due, at least in part, to hemorrhagic activity. Sign of toxicity include hypothermia and tremors. The presence of a toxin in the test material that can cause mortality cannot be ruled out. A protein toxin (28,000 m.v.) lethal to mice upon injection has been found in isolates of B.t. israelensis and also an isolate of B.t. morisonii (personal communication, C.Kawanishi, EPA, RTP). The toxicology branch has asked the Mycogen Corporation for Tier II testing to identify the toxic component for human health hazard assessment purposes.

The anticipated low exposure of mammalian wildlife during application, however, indicates that risk to wild mammals from the proposed uses of M-ONE® insecticide containing B.t. san diego delta endotoxin is minimal to nonexistent.

Aquatic Invertebrate Studies

A 48-hour Daphnia magna exposure to 100 mg/L of the a.i. shows the EC_{50} to be >100mg/L.

In view of the above results, no significant toxicity to aquatic invertebrates is expected for the proposed uses of of M-ONE® insecticide containing B.t. san diego delta endotoxin.

Estuarine and Marine Animal Studies

None submitted. These studies will need to be submitted prior to use of this product on or near estuarine or marine environments.

Nontarget Plant Studies

1. A 96 hour exposure to 100mg/L a.i. (1,500 x application rate) showed no reduction in the growth rate of the green alga Selenostrum capricornutum.

2. Vegetative vigor test (15 day): No abnormal responses were observed in the plants tested (potato, corn, soybean and barley).

COMMERCIAL/FINANCIAL INFORMATION IS NOT INCLUDED

3. Vegetative vigor test (14 day): No abnormal responses were observed in the plants tested (ten crops) with the M-ONE® insecticide liquid formulation.

[redacted] M-ONE® insecticide liquid formulation had no detrimental effect on the growth rate of cabbage.

4. Seed germination/emergence test (10 crops): No adverse effects on seed germination were observed.

In view of the above study results, no significant nontarget plant hazard is expected from the proposed uses of M-ONE® insecticide containing B.t. san diego delta endotoxin.

Honey Bee Studies.

A 48 hour contact study with honey bees exposed to 1 mg/bee showed no detrimental effecs.

In view of the above results, no significant acute honey bee toxicity is expected from the proposed uses of M-ONE® insecticide containing B.t. san diego delta endotoxin.

Nontarget Beneficial Insect Studies

1. Ladybug beetles: the 48-hr acute contact toxicity LD_{50} with 100% a.i. was >0.889 mg/beetle.

2. Parasitic hymenoptera: the 48-hr acute contact toxicity LD_{50} with 100% a.i. was >0.56 mg/insect.

3. Green Lacewing larvae: the 48-hr acute contact toxicity LD_{50} with 100% a.i. was >0.56 mg/insect.

In view of the above results, no significant acute toxicity to predatory beneficial insects is expected from the proposed uses of M-ONE® insecticide containing B.t. san diego delta endotoxin.

101.3.0 Endangered Species Considerations

The Endangered Species Act prohibits testing of any endangered species. It suggests testing of closely related species to determine possible detrimental effects. In order to use M-ONE® insecticide within the habitat of the two endangered beetle species (the Delta Green Ground beetle and the Valley Elderberry Longhorn beetle), Mycogen should test closely related members of these species

and demonstrate a lack of toxicity. Until such data are available, EEB has to assume that the target beetles are the most closely related species tested and that the resulting toxicity constitutes a "may effect" situation to endangered beetle species.

As a result M-ONE® insecticide is not to be used in the following California counties pending results of formal consultation with the U.S. Fish and Wildlife Service:

Butte, Colusa, Glenn, Kern, Merced, Sacramento, Solano, Sutter, Tehema and Yolo

Further definition of the precise locations of the endangered beetle species will have to await the results of the formal consultation with the U.S. Fish and Wildlife Service.

101.4.0 Adequacy of Toxicity Data

The registrant has addressed all of the data requirements outlined in the Pesticide Assessment Guidelines, Subpart M. Although all of the studies are useful for risk assessment, some are of the supplemental category because EPA does not, at the present time, have finalized guidance protocols for certain nontarget species. The nontarget insect testing, for example, was performed following subdivision L guidelines.

The studies submitted are, however, sufficient for assessing risk from the commercial use of a naturally occurring delta endotoxin.

101.5.0 Adequacy of Labeling

The precautionary labeling (see sec. 100.5.0) needs to have the following change:

The statement "Do not contaminate water by cleaning of equipment or disposal of wastes" should be deleted. In its place the following needs to be inserted:

"Do not contaminate water when disposing of equipment washwaters".

In addition, an endangered species restriction should appear on the label (see sec. 101.3.0)

102.0.0 Classification N/A

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103.0.0 Conclusions

EEB has reviewed the proposed registration (sec. 3) of M-ONE® INSECTICIDE (4.5% water dispersible liquid) for use on potatoes, tomatoes, eggplant and elm trees to control Colorado potato beetle larvae and elm leaf beetle larvae and adults. Based upon the available data EEB concludes that the proposed uses provide a minimal risk to nontarget organisms.

EEB cannot complete a risk assessment. EEB will formally consult with the U.S. Fish and Wildlife Service since use of M-ONE® Insecticide may affect two endangered beetle species in the following ten California counties:

Butte, Colusa, Glenn, Kern, Merced, Sacramento, Solano, Sutter, Tehema and Yolo

Zigfridas Vaituzis, Microbiologist
Ecological Effects Branch
Hazard Evaluation Division

Zigfridas Vaituzis 3/7/88

Ray Matheny, Head, Section 1
Ecological Effects Branch
Hazard Evaluation Division

Raymond W. Matheny 3/14/88

Henry C. Craven, Acting Branch Chief
Ecological Effects Branch
Hazard Evaluation Division

Henry T. Craven 3/14/88

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